



DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
College Park, MD 20740

AUG 12 2002

*Rec'd 8/27/02
y'b*

Mr. Harry F. Hester
President
Dee Cee Laboratories, Inc.
304 Dee Cee Court
P.O. Box 383
White House, Tennessee 37188-0383

Dear Mr. Hester:

This is in response to your letters of July 23, 2002 to the Food and Drug Administration (FDA) pursuant to 21 U.S.C. 343(r)(6) (section 403(r)(6) of the Federal Food, Drug, and Cosmetic Act (the Act)).

The product **Guggulextra #868** uses the claim "Nutritionally Supports Healthy Cholesterol Levels." The product **Beta Sitosterol #584** uses the claim "Use as Part of Your Diet to Nutritionally Support Healthy Cholesterol Levels." In the preamble to the January 6, 2000 final rule on structure/function claims (see 65 FR 1000 at 1018), FDA stated that claims about the maintenance of normal cholesterol levels did not necessarily constitute implied disease claims. We stated, however, that because "many people think of cholesterol solely in terms of the negative role of elevated cholesterol in heart disease," in order to avoid implying that the product prevents or treats heart disease, a cholesterol maintenance claim would have to clarify that the product is only for maintenance of cholesterol levels that are already within the normal range. The claims for your products do not establish that the claims are about blood cholesterol levels that are already within normal limits and, therefore, imply that the product is intended to treat elevated blood cholesterol levels and reduce the risk of a disease, namely, coronary heart disease.

The statements that you are making for these products suggest that they are intended to treat, prevent, or mitigate a disease. These claims do not meet the requirements of 21 U.S.C. 343(r)(6). These claims suggest that these products are intended for use as drugs within the meaning of 21 U.S.C. 321(g)(1)(B), and that they are subject to regulation under the drug provisions of the Act. If you intend to make claims of this nature, you should contact FDA's Center for Drug Evaluation and Research (CDER), Office of Compliance, HFD-310, 7520 Standish Place, Rockville, Maryland 20855.

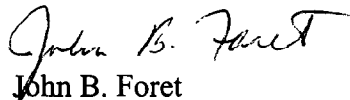
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Page 2 - Mr. Harry F. Hester

Please contact us if we may be of further assistance.

Sincerely,



John B. Foret

Director

Division of Compliance and Enforcement

Office of Nutritional Products, Labeling

and Dietary Supplements

Center for Food Safety

and Applied Nutrition

Copies:

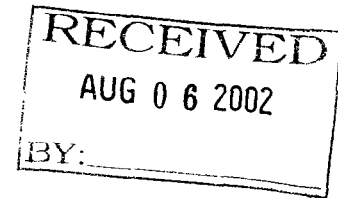
FDA, Center for Drug Evaluation and Research, Office of Compliance, HFD-300

FDA, Office of the Associate Commissioner for Regulatory Affairs, Office of
Enforcement, HFC-200

FDA, Nashville District Office, Office of Compliance, HFR-SE340

DEE CEE LABORATORIES, INC.

304 Dee Cee Court / P.O. Box 383
White House, Tennessee 37188-0383
Phone 615-672-4987



July 23, 2002

CERTIFIED MAIL

7000 0520 0014 9404 3311

Office of Special Nutritionals (HFS-450)
Center for Food Safety and Applied Nutrition
Food and Drug Administration
200 "C" Street, S.W.
Washington, D.C. 20204

Dear Sir:

This notification is on behalf of Dee Cee Laboratories, Wonder Laboratories and Foster Regal Laboratories, manufacturer and distributors, 304 Dee Cee Court, White House, TN, 37188.

We intend to include the following statement of nutritional support on our BETA SITOSTEROL, #584, a dietary supplement containing Beta Sitosterol.

"Use as Part of Your Diet to Nutritionally Support
Healthy Cholesterol Levels"

Please be advised that the information contained herein is, to the best of our knowledge and information, accurate. Our firm has information substantiating that the above statement is truthful and not misleading.

Respectfully submitted,

DEE CEE LABORATORIES, INC.

Harry F. Hester
Harry F. Hester, President

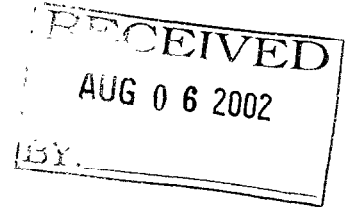
HFH/ss

betasit.fda

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DEE CEE LABORATORIES, INC.

304 Dee Cee Court / P.O. Box 383
White House, Tennessee 37188-0383
Phone 615-672-4987



July 23, 2002

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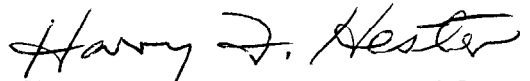
We intend to include the following statement of nutritional support on our GUGGULXTRA, #868, a dietary supplement containing Guggul Extract.

"Nutritionally Supports Healthy Cholesterol Levels"

Please be advised that the information contained herein is, to the best of our knowledge and information, accurate. Our firm has information substantiating that the above statement is truthful and not misleading.

Respectfully submitted,

DEE CEE LABORATORIES, INC.


Harry F. Hester, President

HFH/ss

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